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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,140	08/08/2001	Preeti Lal	PF-0512-1 DIV	3400

27904 7590 12/18/2002

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EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/925,140

Applicant(s)

LAL ET AL.

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18,27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,8,13-18,27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-7,9,11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

1. Claims 3-5, 9, 11, 12 have been amended.
2. Claims 1-2, 8, 10, 13-18, 27-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions. Applicant timely traversed the restriction (election) requirement in Paper No. 6.
3. Claims 3-7, 9, 11, and 12 are under examination.
4. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action
5. The following Office Action contains some NEW GROUNDS of rejection.

Rejections Withdrawn

6. The rejection of claims 3-7, 9, 11, and 12 under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility is withdrawn in view of arguments that the polypeptide is an enzyme and the enzyme is decreased in colon carcinoma and sarcoma and altered levels are associated with obesity and diabetes.
7. The rejection of claims 3-7, 9, 11, and 12 under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention is withdrawn in view of the withdrawn 101 rejection above.

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8. The rejection of claims 11-12 under 35 U.S.C. 102(b) as being anticipated by Iwahori et al (WO 94/03599, published 2/17/94) is withdrawn in view of the amendments to the claims.

9. The rejection of claims 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Accession Number AA573827 is withdrawn in view of the amendment to the claims.

10. The rejection of claims 11-12 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn.

Response to Arguments

11. The rejection of claims 3-7, and 9 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained.

The response filed 11/4/02 has been carefully considered but is deemed not to be persuasive. The response states the specification teaches an activity for SEQ ID NO:1 and as such one could screen for variants of such and biologically active fragments of such because SDHH is homologous to SDH and has regions that are known for enzymatic activity in SDH (see page 22-23 of response) and immunologically active fragments can be selected based on the fact that one would be directed away

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from hydrophobic regions of the peptide (see page 24). In response to these arguments, while the specification teaches an assay for enzymatic activity the claims recite "biologically active" and in view of the indefiniteness of this phrase (see below) it is not clear if the biologically active fragments are enzymatically active or some other activity. Thus one would not be able to determine biologically active fragments. In addition, it is not clear that the enzymatic activity of SDHH is contained in a continuous polypeptide fragment or the activity is composed of many areas of the protein which are needed for proper folding to obtain enzymatic activity and as such not just any polynucleotide of 60 nucleotides that encodes a fragment of SEQ ID NO:1 would have enzymatic activity and as such it would require undue experimentation to determine all such fragments. While one can screen for enzymatic activity the claims encompass variants that are 90% identical that do not have any function (see claim 3(b) for example) and as such one would not know how to use such polynucleotides. With regard to immunogenic fragments, the claims encompass any fragment even those that are a single amino acid and as such antibodies to such would not be used for detection of the specific protein of SEQ ID NO:1 and therefore one would not know how to use the invention.

Thus, undue experimentation would be required to use the instantly claimed polypeptides.

The following are some NEW GROUNDS of rejections

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 3, 6, 7, 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 3, 6, 7, and 9 are indefinite for reciting "biologically active" in claims 3 and 9 because the exact meaning of the phrase is not clear. Does the phrase mean enzymatically active as serine dehydratase activity or some other activity?

Claim Rejections - 35 USC § 112

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 3, 6-7, 9, 11-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The claims are broadly drawn to polynucleotides encoding polypeptides which are naturally occurring with 90% identity to SEQ ID NO:1, biologically active fragments of SEQ ID NO:1, immunogenic fragments of SEQ ID NO:1, and at least 60 contiguous nucleotides encoding a fragment of SEQ ID NO:1 with serine dehydratase activity.

With the exception of SEQ ID NO:1 the specification does not teach any other fragments that are biologically active or have serine dehydratase activity or regions of SEQ ID NO:1 that contain serine dehydratase activity. While the response filed 11/4/02 does state that specific regions of the protein responsible for its biological activity is disclosed (see page 23 of response) on page 1, lines 15-17, this disclosure only discloses motifs that are common to SDH and it is not clear which regions are required for enzymatic activity. In addition the response states that there is a highly conserved region thought to be the active site for the dehydration reaction in human SDH and this site is well conserved in SDHH but again it is unclear if this region as well as the pyridoxyl attachment site is needed for enzymatic activity. The specification does not disclose which region of 60 nucleotides would encode a fragment that would have serine dehydratase activity. The claims also encompass naturally occurring amino acids that are 90% identical to SEQ ID NO:1, however, the specification only discloses SEQ ID NO:1.

The general knowledge in the art concerning variants does not provide any indication of how the structure of one variant is representative of unknown variants. Reiger et al. (Glossary of Genetics and Cytogenetics, Classical and Molecular, 4th Ed., Springer-Verlag, Berlin, 1976) clearly define alleles as one of two or more alternative

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forms of a gene occupying the same locus on a particular chromosome... and differing from other alleles of that locus at one or more mutational sites (page 17). Thus, the structure of naturally occurring sequences are not defined. With the exception of SEQ ID NO:1 the skilled artisan cannot envision the detailed structure of the encompassed polypeptides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation.

Thus, one of skill in the art would not understand that the applicant had possession of the claimed invention at the time the instant application was filed.

Conclusions

16. No Claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of

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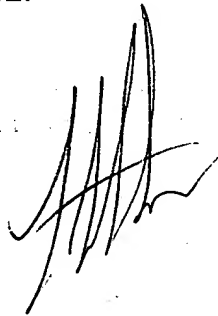
this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

18. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879

A handwritten signature in black ink, consisting of several vertical, slightly curved strokes, followed by a horizontal line and a small flourish at the end.